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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,358	02/15/2001	Gregory Donoho	LEX-0134-USA	2856

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LEXICON GENETICS INCORPORATED
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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,358

Applicant(s)

DONOHO ET AL.

Examiner

Sheridan K Snedden

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-4 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application)
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 and 8 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, drawn to a isolated nucleic acid encoding the amino acid sequence of SEQ ID NO: 2, classified in class 536, subclass 23.5.
 - II. Claim 4, drawn to a isolated nucleic acid encoding the amino acid sequence of SEQ ID NO: 16, classified in class 536, subclass 23.5.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid molecules of invention I and II, while having overlapping structural similarities, encode for alternative proteins as disclosed on page 2, line 2 of the specification. These proteins or nucleic acids are not shown as capable of use together, but may be used in materially different processes. Therefore, invention I and II are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

2. A telephone call was made to Lance Ishimoto on August 13, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

During a telephone conversation with Lance Ishimoto on 13 August 2002 a provisional election was made without traverse to prosecute invention I, claims 1-3. Affirmation of this

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election must be made by applicant in replying to this Office action. Claim 4 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 1-3 are pending in the application.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The above claims are directed to the nucleic acid sequence of SEQ ID NO: 1, which encodes the amino acid sequence of SEQ ID NO: 2. The nucleic acid above is disclosed as having utility as hybridization probes in screening libraries (page 5, line 2), to identify and characterize expression of a gene (page 5, line 29), to validate novel targets in drug discovery (page 6, line 29), or may be useful in encoding antisense molecules for the regulation of a gene (page 7, line 37). Similarly, the polypeptide encoded by the nucleic acid above is disclosed as having a probable utility as a therapeutic (page 13, line 29). Of the above uses, none provide a specific or substantial asserted utility or a well established utility. Basic research, such as studying the properties of the claimed product itself or the mechanisms in which the material is involved, such as gene expression, does not constitute specific or substantial utilities. The therapeutic utility disclosed in the specification teach the treatment of unspecified disease or condition. Specifically, the specification merely states that the nucleic acids may be used to screen collections of genetic material from patients who have a particular medical condition (page 7, line 2). Neither the specification nor the art of record disclose any diseases or

conditions caused or exacerbated by the nucleic acid of SEQ ID NO: 1. The asserted utility in this case essentially is a method of screening an unspecified, undisclosed disease or condition, which does not define a "real world" context of use. Screening an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use.

Additionally, the use of the nucleic acid in the method of making a polypeptide that itself has no specific and substantial asserted or well established utility is itself not specific and substantial or well establish. The specification as filed does not disclose or provide any evidence that points to an activity for the protein and furthermore there is no art of record that discloses or suggests any activity for the claimed protein. The specification discloses the polypeptide of SEQ ID NO: 2 as having potential utility as a therapeutic (page 13, line 29). Further experimentation is required to identify a specific and substantial use for the polypeptide as only prophetic uses not yet evaluated are disclosed in the specification. Furthermore, the non-prophetic uses disclosed for the polypeptide, *e.g.* generating antibodies, do not show specific utility as this is a general use of all polypeptides.

Thus, the claimed polynucleotide encoding protein is not supported by either a specific and substantial asserted utility or a well established utility as to the above because the specification fails to assert any well established utility for the protein and neither the specification as filed nor any art of record disclose or suggest any activity for the protein such that any utility would be well established for the protein.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 is indefinite because it is unclear as to what conditions are considered "stringent." The specification provides an example of "stringent conditions" (see page 3, lines 34-37), however, this example is not defining.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Mahairas *et al.* (Proc Natl Acad Sci U S A. 1999 Aug 17;96(17):9739-44). Mahairas *et al.* teach an isolated nucleic acid molecule comprising at least 24 contiguous bases as compared to SEQ ID NO: 1 of the instant application (see Accession No: AQ743958). The nucleic acid sequence taught by Mahairas *et al.* is identical to SEQ ID NO: 1 from base pairs 1806 to 1980. Thus, the reference anticipates the claimed invention.

7. Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by Bonaldo *et al.* (Genome Res. 1996 Sep;6(9):791-806). Bonaldo *et al.* teaches an isolated nucleic acid molecule comprising at least 24 contiguous bases as compared to SEQ ID NO: 1 of the instant application (see Accession No: BF543337). The nucleic acid sequence taught by Bonaldo *et al.* is identical to SEQ ID NO: 1 from base pairs 247 to 284. Thus, the reference anticipates the claimed invention.

Advisory Information

8. None of claims 1-3 are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 746-3975 for regular communications and (703) 746-3975 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS

August 22, 2002

SKS


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600